

## THERAPEUTIC DRUG MONITORING PROCESS

### 1. Verify or request order for collecting serum drug levels



#### Criteria\* for Considering Therapeutic Drug Monitoring on TB patients



Bacteriologic Considerations	Medical Considerations	Clinical Considerations	Considerations based on TB Diagnosis**
<p>Slow response to adequate therapy at 4-8 weeks of treatment, evidenced by the following:</p> <ul style="list-style-type: none"> <li>• Patient remains AFB sputum smear positive at 4-8 weeks,</li> </ul> <p>and/or</p> <ul style="list-style-type: none"> <li>• Sputum smear results not decreasing adequately (4+ to 3+, 2+ to 1+, etc.)</li> </ul>	<ul style="list-style-type: none"> <li>• TB/diabetes comorbidity: Serum drug levels can be drawn two weeks after initiation of adequate therapy</li> <li>• Mal-absorption due to chronic or acute co-morbidity</li> <li>• Chronic or excessive vomiting or diarrhea</li> <li>• HIV infection and CD-4 count &lt;100**</li> <li>• Low or high body mass index (&gt;10% above or below ideal body weight)</li> </ul>	<ul style="list-style-type: none"> <li>• No improvement or worsening of TB symptoms (i.e. no weight gain, no reduction in cough, etc.)</li> <li>• Worsening CXR anytime during course of adequate therapy</li> <li>• New clinical deterioration, likely related to TB (i.e. new evaluation for TB relapse or concern for drug resistance**)</li> </ul>	<ul style="list-style-type: none"> <li>• Patient Relapse: When signs and symptoms of TB return within two years of a prior episode of disease; serum drug levels can be drawn two weeks after initiation of therapy</li> <li>• When second line medications need monitoring (i.e. Cycloserine, which has a narrow therapeutic range and potential for toxicity)</li> <li>• TB meningitis</li> </ul>

\* **Therapeutic Drug Monitoring should be reserved for patients who are not responding to adequate therapy, and not necessarily for patients who meet some of the stated criteria and are otherwise doing well.**

\*\* Consultation recommended by a DSHS recognized Medical Consultant, see list here:

[www.dshs.texas.gov/idcu/disease/tb/consultants/](http://www.dshs.texas.gov/idcu/disease/tb/consultants/)

## THERAPEUTIC DRUG MONITORING PROCESS

### 2. Contact the DSHS TB and Hansen's Disease Branch for billing instructions



**Email a request to order serum drug levels to:** [elizabeth.foy@dshs.texas.gov](mailto:elizabeth.foy@dshs.texas.gov), or fax request to #512-533-3167 attention: TB Program (Phone 512-533-3000).

Once completed, the submitter will be sent the ***National Jewish Laboratory Requisition*** which includes DSHS Billing Information

### 3. Arrange timing of the blood draw and directly observed therapy (DOT) according to which drug/s are being tested

#### Steps to collecting serum drug levels

#### Step 1

**Perform Directly Observed Therapy (DOT) of TB medications being tested, ensuring that the blood draw can occur at the indicated time *after* the dose of medication is observed.**

- Timing of draws per drug can be found on the National Jewish Laboratory requisition\*. Time of dose and draw must be written on form.

\* The requisition states the name of the drug and hour duration of when to draw the peak level, i.e. "Rifabutin 3h". If peak Rifabutin levels were being tested, the DOT provider would observe the patient taking their current dose of Rifabutin, wait three (3) hours, and draw the blood as specified.

5. THERAPEUTIC DRUG MONITORING			
Time after the dose to collect "peak" concentrations is shown in parentheses after each drug name and sample may be collected 4 hours after the "peak". Trough concentrations (prior to next dose) are recommended for the anti-HIV and anti-fungal drugs.			
Rifampin (2-4h)	<input type="checkbox"/> LFLHL	Levofloxacin (2h)	<input type="checkbox"/> RBN Rifabutin (3h)
Linezolid (2h)	<input type="checkbox"/> ILN7I	Linezolid (2h)	<input type="checkbox"/> RIFH Rifampin (2h)

## THERAPEUTIC DRUG MONITORING PROCESS

### Step 2

**Perform phlebotomy and collect blood in an 8-10 ml plain Red Top tube.** (Also acceptable is an 8-10 ml Green Top tube, but it is not preferred.)

- Preferred volume is at least 2 ml of serum per test for adults, 0.5 ml for pediatrics.
- Document timing of the blood draw on the requisition.
- Use a separate tube for each test ordered. Allow room for expansion of sample.

### Step 3

**Centrifuge immediately, and aliquot serum into a labeled polypropylene or similar plastic tube, using one tube per test; or, coordinate processing with a local laboratory.**

- Centrifuging should occur within 2 hours of collection, preferred in 30 mins. Draw blood, allow 20 minutes to clot, and then centrifuge. If blood will be processed in a local laboratory and not by collector, it can be kept on ice while in transport. Coordinate with lab to ensure timely processing.
- A pipette can be used to aliquot separated serum into the polypropylene tube.
- The 50ml conical tubes for sputum collection are made of polypropylene and can be used for decanted serum.

### Step 4

**Ensure separated serum is frozen (or kept refrigerated until freezing) to prepare for shipping.**

- Freeze at -70C if possible, but at minimum -20C.
- If an ultralow freezer is unavailable, the serum can be frozen in a regular freezer; do not allow it to go through a defrost cycle.
- Alternately, the tube with decanted serum can be placed on a rack and stored on dry ice (the rack should prevent direct contact between the tube and the ice; the serum will slowly freeze without being shocked by contact with the dry ice).

## THERAPEUTIC DRUG MONITORING PROCESS

### 4. Send/Ship Serums to National Jewish Laboratory

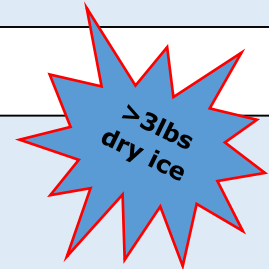
#### Fully complete the National Jewish Laboratory Requisition. Include:

- Drug dosage, frequency, method of administration, and date and time of last dose prior to draw



#### Ship samples via overnight delivery on *at least 3 lbs* of dry ice.

- Ship samples to be received Monday through Friday
- Do not ship on Friday or Saturday, or the day prior to a holiday
- Package properly for dry ice handling\*, including using a dry-ice specific label, and a return label for box to be shipped back to sender



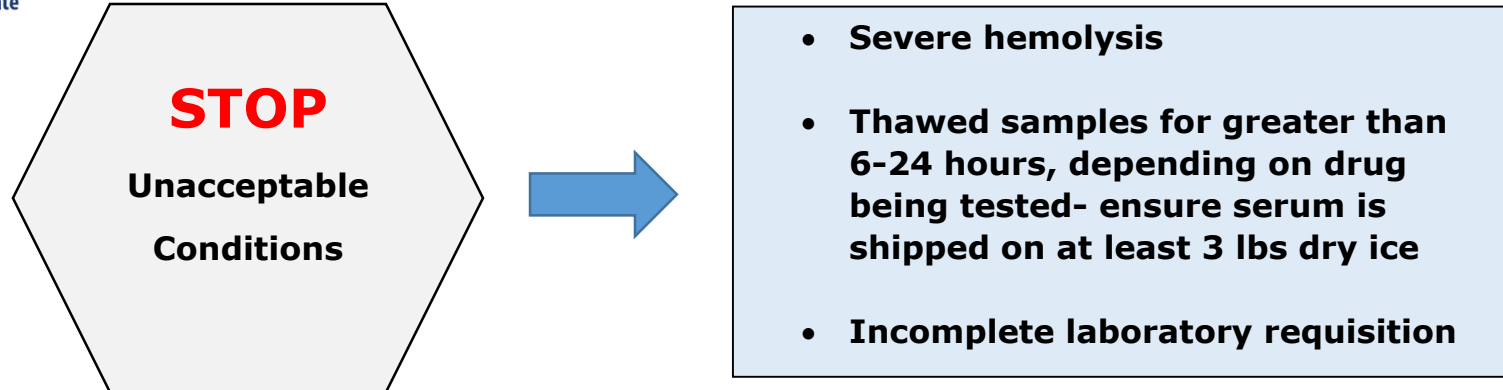
*\*Not all couriers will ship dry ice, check before sending. Full shipping guidelines can be found on the National Jewish website:  
[www.nationaljewish.org/for-professionals/diagnostic-testing/adx/diagnostic-testing/shipping-guidelines](http://www.nationaljewish.org/for-professionals/diagnostic-testing/adx/diagnostic-testing/shipping-guidelines)*



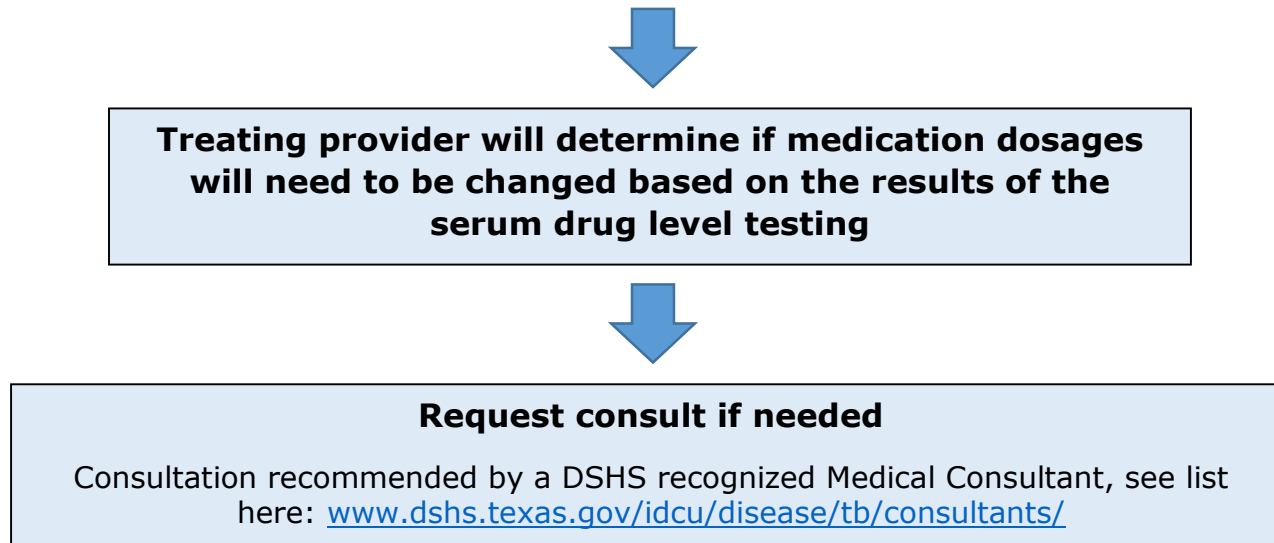
Ship to:

**National Jewish Health**  
Pharmacokinetics Laboratory  
1400 Jackson Street, K425  
Denver, CO 80206

## THERAPEUTIC DRUG MONITORING PROCESS



### 5. Respond to results as appropriate



## THERAPEUTIC DRUG MONITORING PROCESS

### Helpful Links

National Jewish Laboratory Requisition:

[www.nationaljewish.org/getattachment/professionals/clinical-services/diagnostics/adx/ordering-tests/requisitions/Pharmacokinetics-requisition.pdf.aspx](http://www.nationaljewish.org/getattachment/professionals/clinical-services/diagnostics/adx/ordering-tests/requisitions/Pharmacokinetics-requisition.pdf.aspx)

Instructions per drug (type in drug name being tested in Search box):

[www.nationaljewish.org/for-professionals/diagnostic-testing/adx/search-adx-tests?ref=bottom](http://www.nationaljewish.org/for-professionals/diagnostic-testing/adx/search-adx-tests?ref=bottom)

Shipping Guidelines:

[www.nationaljewish.org/for-professionals/diagnostic-testing/adx/diagnostic-testing/shipping-guidelines](http://www.nationaljewish.org/for-professionals/diagnostic-testing/adx/diagnostic-testing/shipping-guidelines)

DSHS Recognized Medical Consultants:

[www.dshs.texas.gov/idcu/disease/tb/consultants/](http://www.dshs.texas.gov/idcu/disease/tb/consultants/)

## THERAPEUTIC DRUG MONITORING PROCESS

**Advanced Diagnostic Laboratories National Jewish Health®**  
Pharmacokinetics Laboratory | 800.550.6227, Option 6 phone | 303.270.2124 fax | njlabs.org

SHIP TO: National Jewish Health  
Pharmacokinetics Laboratory  
1400 Jackson Street, K425  
Denver, CO 80206

Assays may require up to seven business days for completion. Please submit a separate requisition for each sample collection time.

1. PATIENT INFORMATION					
Patient Name (Last, First)			<input type="checkbox"/> Male <input type="checkbox"/> Female	DOB	
2. BILLING INFORMATION - INSTITUTIONAL BILLING ONLY					
National Jewish Health Advanced Diagnostic Laboratories does not bill patients directly or third-party health insurance. Visit njlabs.org or call for details.					
Account Name			Account Name		
Address			Address		
City			State		Zip
Billing Contact Name			Secure Fax		
Phone			Fax		Secure Fax
3. REPORT DELIVERY INFORMATION					
Duplicate Report Requested			Name		
Phone			Fax		Secure Fax
4. SPECIMEN INFORMATION					
Submitted By		Phone		Submitter Specimen #	
Specimen Source					
Required	Drug 1	Drug 2	Drug 3	Drug 4	
Drug name to be tested					
Specimen (Serum, CSF, Plasma, Other)					
Drug dose (mg) (Specify: PO, IV, IM)					
# Doses per week					
Date of last dose					
Time of last dose (For IV: Start/End)					
Date blood drawn					
Time blood drawn					
5. THERAPEUTIC DRUG MONITORING					
Please provide 2 mL serum per test. The number of hours after the dose to collect "peak" concentrations is shown in parentheses after each drug name, if applicable. To test for delayed drug absorption, a second sample may be collected 4 hours after the "peak". Trough concentrations (prior to next dose) are recommended for the anti-HIV and anti-fungal drugs.					
<input type="checkbox"/> ABALH	Abacavir (1-2h)	<input type="checkbox"/> DARU	Darunavir (2-4h)	<input type="checkbox"/> LFLHL	Levofloxacin (2h)
<input type="checkbox"/> AMXLB	Amoxicillin	<input type="checkbox"/> DELV	Delavirdine (2h)	<input type="checkbox"/> LNZN	Linezolid (2h)
<input type="checkbox"/> AMPL	Amprenavir (2-3h)	<input type="checkbox"/> EFVL	Elavirenz (5h)	<input type="checkbox"/> LOPV	Lopinavir (4-6h)
<input type="checkbox"/> ATAZ	Atazanavir (2h)	<input type="checkbox"/> EMH	Emtricitabine (1-2h)	<input type="checkbox"/> MXFL	Moxifloxacin (2h)
<input type="checkbox"/> AZL	Azithromycin (2-3h)	<input type="checkbox"/> EMBH	Ethambutol (2-3h)	<input type="checkbox"/> NLFL	Nelfinavir (2-3h)
<input type="checkbox"/> CFH	Clofazamine (2-3h)	<input type="checkbox"/> ETAH	Ethionamide (2h)	<input type="checkbox"/> NEV	Nevirapine (2h)
<input type="checkbox"/> CLART	Clarithromycin (2-3h)	<input type="checkbox"/> FLUCZ	Fluconazole (2h)	<input type="checkbox"/> OFLHL	Ofloxacin (2h)
<input type="checkbox"/> CMH	Capreomycin (1-2h)	<input type="checkbox"/> INDOL	Indinavir (1-2h)	<input type="checkbox"/> PASH	P-Aminosalicylic Acid (8h)
<input type="checkbox"/> CIPH	Ciprofloxacin (2h)	<input type="checkbox"/> INH	Isoniazid (1-2h)	<input type="checkbox"/> POSA	Posaconazole (3-6h)
<input type="checkbox"/> CORTH	Cortisol (prednisolone)	<input type="checkbox"/> ITRL	Itraconazole (3-4h)	<input type="checkbox"/> PZAH	Pyrazinamide (2h)
<input type="checkbox"/> CSH	CycloSERINE (2-3h)	<input type="checkbox"/> LAMLH	Lamivudine (1h)	<input type="checkbox"/> RALH	Raltegravir (3h)
<input type="checkbox"/> RBN	Rifabutin (3h)	<input type="checkbox"/> RIFH	Rifampin (2h)	<input type="checkbox"/> RFPTN	Rifapentine (5h)
<input type="checkbox"/> RTVL	Ritonavir (2-3h)	<input type="checkbox"/> SAQL	Saquinavir (2-3h)	<input type="checkbox"/> SILH	Sildenafil (1-2h)
<input type="checkbox"/> STVLH	Stavudine (1h)	<input type="checkbox"/> SMH	Streptomycin (1-2h)	<input type="checkbox"/> TIPV	Tipranavir (3h)
<input type="checkbox"/> VORZ	Voriconazole (2h)				
6. SPECIAL INSTRUCTIONS					
Please list additional medications patient is currently taking here.					
Sample preparation and shipment: Collect in a plain red top, 8-10 mL tube. Separate serum from cells immediately by centrifugation and aliquot into a labeled polypropylene or similar plastic tube. Use a separate tube for each test ordered. Allow room for expansion of sample inside tube. Freeze at -20°C if possible (otherwise -20°C). Ship on ≥ 3 lbs. dry ice via overnight transport. SHIP SAMPLES TO BE RECEIVED MONDAY THROUGH FRIDAY. DO NOT SHIP ON FRIDAY OR SATURDAY.					
INTERNAL USE					
Received By	Date	Time	Condition: <input type="checkbox"/> Frz <input type="checkbox"/> Ref <input type="checkbox"/> Thawed		

**Billing Information:** Request from DSHS Tuberculosis and Hansen's Disease Branch via Lara Miller (see page 2 of process).

**Report Delivery Information:** Local (LHD) or Regional Health Department (HSR) information here. **Make sure fax number is correct** to ensure results are returned to sender.

**Submitter Specimen #:** Can be any ID that the LHD or HSR uses to identify patient specimen; leave blank if none.

**Submitted By:** place the name of the LHD or HSR contact person (i.e. Nurse Case Manager for the patient). Also include contact # of the submitter.

**All other sections must be filled out, including patient information, which drugs are being tested, times of dosing, etc.**